K034046

3/10/04

RNK Products

510(k) SUMMARY
RNK Products
Telephonic Stethoscope TR-1

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K034046

Submitter Information

Submitter:	RNK Products 12700 Diamond Drive Burnsville, MN 55337 Telephone: (612) 414-0289 Facsimile: (952) 894-2623
Contact Person:	Charles Richard Abbruscato RNK Products Telephone: (612) 414-0289 Facsimile: (952) 894-2623
Date Prepared:	December 19, 2003

Device Information

Name of Device	RNK Telephonic Stethoscope Model TR-1
Common or Usual Name	Electronic Stethosocpe
Classification Name	Electronic Stethosocpe
Predicate Devices	American TeleCare's CareTone II and CareTone II/LBR (Marketed as CareTone Ultra) Digital Telephonic Stethoscopes

Device Description

The RNK Telephonic Stethoscope Model TR-1 consists of a Chest Piece Assembly, a standard audio Headset, a wall-mount power adapter and an electronics Module containing amplifiers, filters, CODEC, UART and RS232 interface. The power adapter, Chest Piece Assembly and Headset are detachable and can plug into the electonics Module. The electronics Module is capable of operating as a transmitting unit sending digitized auscultation signals from the attached Chest Piece, or as a receiving unit accepting the digitized auscultation signals, converting them to analog audio and presenting them to the attached Headset.

The RNK Telephonic Stethoscope TR-1 is substantially equivalent to American TeleCare's CareTone II Digital TelePhonic Stethoscope (K963678) and American TeleCare's CareTone II/LBR TelePhonic Stethoscope (marketed as the CareTone Ultra) which was included with the Digital PTM (K973873).

The RNK Telephonic Stethoscope TR-1 has the same intended use, principles of operation and technological characteristics as the predicate devices. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2004

RNK Products
c/o Mr. Charles Richard Abbruscato
President
12700 Diamond Drive
Burnsville, MN 55337

Re: K034046
Trade Name: RNK Telephonic Stethoscope, Model TR-1
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: II (two)
Product Code: DQD
Dated: December 19, 2003
Received: December 29, 2003

Dear Mr. Abbruscato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034046

Device Name: TR-1 Telephonic Stethoscope

Indications For Use:

The RNK Telephonic Stethoscope Model TR-1 is intended for use to transmit auscultation sounds, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communications channel between the two locations.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K034046